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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,621	07/06/2005	James C Jensen	Nutri-Check-USNP	8393

33549 7590 09/03/2009

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EXAMINER	
FISHER, ABIGAIL L	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,621	JENSEN ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-20,43-46,54-69,73-82,105,106,110-113 and 132-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-20,43-46,54-69,73-82,105,106,110-113 and 132-136* is/are rejected.

7)☒ Claim(s) *132* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on May 29 2009 is acknowledged. Claims 1-9, 21-42, 47-53, 70-72, 83-104, 107-109, 114-131 and 137-189 were/stand cancelled. Claims 10, 12, 18-20, 43, 45-46, 60-63, 69, 78, 80-81, 105-106, 110-113, 132-136 were amended. Claims 10-20, 43-46, 54-69, 73-82, 105-106, 110-113 and 132-136 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

A second action non-final is deemed necessary as instant claims 67-68 were inadvertently left out of the previous office action.

Claim Objections

The objection of claims 10 and 18 because of informalities is **withdrawn** in light of Applicants' amendments filed on May 29 2009.

Claim 132 is objected to because of the following informalities: chromatography is incorrectly spelt in line 3 as chromatagraphy. Appropriate correction is required.

Specification

The amendment filed May 29 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “has lower correlation". Applicants’ amendment is attempting to incorporate this language into the specification. However, this language or idea was not present in the application at the time of filing.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 110-112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 110-112 introduce new matter as the claims recite the limitation: "lower correlation”. There is no support in the specification for this limitation. The limitation of: "lower correlation" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant’s disclosure a description of the invention as

presently claimed. The specification discloses the tests being highly correlated with the supplement but does not describe the instantly claimed limitation. There is no guidance in the specification to select lower correlation and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18-20, 46, 54-69, 73-82, 105-106, 110-113 and 132-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The specification (by way of the prior art), while being enabling for a calcium supplement and pH test strip, a blood glucose monitor and an insulin (supplement) and a peak expiratory flow device with the appropriately prescribed medication does not reasonably provide enablement for a method of making a supplement available containing a separate amount of said supplement and a separate test modality. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope

with these claims. Specifically, the instant specification has not described or enabled the combination of supplement and test modality other than what is described above.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Formal, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re

Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, relative skill level, and breadth of the claims

The instant invention is directed to a method of making a supplement available comprising the steps of: containing a separate amount of said supplement by a distribution container; selecting a separate test modality relevant to some aspect in conjunction with use of said supplement; establishing a producer for use of said separate test modality; compactly assembling said separate test modality; and providing said compactly assembled separate test modality for distraction in association with said distraction container.

The complex nature of the claims is greatly exacerbated by the breath of the claims. The instant claims recite any supplement in combination with any test modality. The relative skill of those in the art is high, that of an MD or PHD.

The state and predictability of the art

The state of the art recognizes utilizing pH strips in combination with a chewing gum. As illustrative of the state of the art, the examiner cites Azar et al. (USPGPUB No. 20010012636, cited in the Office action mailed on 9/30/09), a glucose monitor in combination with insulin therapy (Beckers US Patent No. 5019974) and a peak expiratory flow rate in combination with prescribed medication (Kaish US Patent No.

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[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

5501231). In these cited references the objective of the test and the supplement is clearly indicated. The glucose monitor measures blood sugar levels to indicate when insulin needs to be administered, the pH test strips indicate when gum needs to be chewed, and the peak expiratory flow rate machine monitors a patient's respiratory system in combination with the prescribed medication.

The lack of significant guidance from the specification or the prior art with regard to utilizing any test modality with any supplement makes practicing the scope of the invention unpredictable.

The amount of direction or guidance provided and the presence or absence of working examples and the quantity of experimentation necessary

The specification provides no direction or guidance for utilizing any supplement with any test modality. The only specific combination taught is pH test strips and calcium supplements. Due to the vastness of compounds classified as supplements, as this term includes herbs, pharmaceuticals, cosmetic active, any ingredient with a biological effect and the vastness of test modalities one of ordinary skill would undergo undue experimentation in deducing which supplements can be used with what particular test modalities within applicant's scope.

There are no working examples in the specification. The descriptions of the particular test modalities suggested by the instant specification and claimed only refer to the test by name. However, this name does not describe the test nor teach one of ordinary skill in the art what the test is actually testing for except for pH test strips as that name provides enough guidance to one of ordinary skill in the art what is actually

being tested. In *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 Fed. Cir. 1997 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." (emphasis added). The instant specification provides no guidance as to the correlation between pH test strips and calcium supplements, the examiner determined this connection via teachings of the prior art. Therefore, one of ordinary skill in the art would have to undergo undue experimentation as they would first have to determine which supplement would be prescribed then determine which test if any can be used in conjunction. This is tantamount to undue burden.

Conclusion

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed supplement can be use din combination with some particular test modality as inferred by the claim and contemplated by the specification. The instant specification provides no guidance as to what the test modalities actually test for nor how they are correlated to supplements. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 18-20, 43, 45, 69, 73-82, 105-106, 110-113, 132-134 and 136 are

rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses tests, such as pH test strip which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) **43, 45, 69, 73-82, 105-106, 110-113, 132-134 and 136** is(are) directed to encompass **any test modality, test strip, on-site test, send-in test, supplement need indicative test, supplement efficacy based test, user profiled test, the tests of claim 78, qualitative test, semi quantitative test, etc. (those tests of claim 105), personal baseline test, tests of claim 132, saliva sensitive test, urine based test, hair based test, nail based test, non-invasive test, blood-based test, and tests of claim 135 as well as a variety of different procedures such as time of day based procedure, same time of day test procedure, morning based test procedure, etc. (specifically those of claim 69).** None of these tests meet the written description provision of 35 USC § 112, first paragraph, due to any information as to what the test is actually testing for or how its performed and tests are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the

filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice…. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing “sufficiently detailed, relevant identifying characteristics,” including “functional characteristics when coupled with a known or disclosed correlation between function and structure.” Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

The instant specification provides not description for what the test is actually testing for. A ph test is a sufficient description for this particular test as a pH range is small enough that one of ordinary skill in the art would know what is being tested. However this is not true for the other tests taught. For example in the AIDS based test, is the test for determining whether or not someone has AIDS or is it testing for a specific antibody. The specification provides no description for these tests other than the names. Furthermore, the claims recite procedures that are to be performed but the specification provides no description as to what these procedures are or what they are supposed to accomplish. Therefore, only the above specifically described test the pH test strip, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-20, 43-46, 54-69, 73-82, 105-106, 110-113 and 132-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 as currently written is vague and indefinite. The claim recites a "separate calcium supplement" and a "separate saliva pH test strip". It is unclear what is meant by separate. Do applicants mean physically separate from other things in the system? If so then what is an amount of a separate calcium supplement.

Claim 18 as currently written is vague and indefinite. The claim recites a "separate amount of said supplement" and a "separate test modality". It is unclear what is meant by separate. Do applicants mean physically separate from other things in the system? If so then what is separate amount of said supplement. Separate from what?

Claim 18 as currently written is vague and indefinite. The claim recites a method of making a supplement available. However, the claim does not indicate who or what the supplement is made available. Therefore, the scope of the claim is unclear.

Claim 43 as currently written is vague and indefinite. The claim recites a "separate amount of said supplement". It is unclear what is meant by separate. Do applicants mean physically separate from other things in the system? If so then what is separate amount of said supplement. Separate from what?

Claim 69 as currently written is vague and indefinite. The claims recite various different test processes. However, it is unclear what these processes/procedures are referring to. Is this the time of the day the test is performed, or do the times indicated in the title refer to a specific part of the procedure? The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for procedure.

Claim 78 as currently written is vague and indefinite. The claims recite various user profiled test. It would appear that a children-target test would be directed to those

people who are children. However, what is a prior history target test, symptomatic target test and prior blood test result. The instant specification does not describe these particular tests. Therefore what is the prior history, symptoms or blood tests that is targeted? The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for users targeted.

Claim 105 as currently written is vague and indefinite. The claim recites a variety of different tests such as qualitative test, semi-quantitative test, quantitative test, rate of change test, absolute value test, relative value and fail safe test. However, the instant claim and the specification provide no description or explanation as to what these test pertain to. The terms qualitative, semi-quantitative, quantitative, rate of change, relative value and fail sate are relative terms which renders the claim indefinite. The term terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant specification provides not explanation as to what differentiate a absolute value test from quantitative, etc. The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for different tests.

Claim 106 as currently written is vague and indefinite. The term "highly correlates" in claim 106 is a relative term which renders the claim indefinite. The term "highly correlates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant claim indicates

that a certain correlation is desired however what the correlation is or what amount of correlation would lead to something being highly correlated is not discussed or contemplated.

Claims 110-112 as currently written are vague and indefinite. The term "lower correlation" in claims 110-112 is a relative term which renders the claim indefinite. The term "lower correlation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant claim indicates that a certain correlation is desired however what the correlation is or what amount of correlation would lead to something having lower correlation is not discussed or contemplated. Furthermore, the instant specification and claims give no guidance as to what distinguishes a test from being lower correlated as opposed to higher correlated.

Claim 132 as currently is vague and indefinite. The claim recites a variety of different tests. However, neither the instant claim nor the instant specification indicates what these test are actually testing for. For example is a dye based test, testing for a particular dye or is it using a dye for testing. What is a chromatography based test? Is it using chromatography? If so then what does it test for? It is difficult to determine if the tests claimed are utilizing what is described in the name or it is testing for what is used in the name.

Claims 133-134 as currently written are vague and indefinite. The claims recite specific tests. However, it is unclear if the tests are testing for the presence of saliva,

urine, hair, nail and blood or if this is location that the test is utilized such as a urine test strip.

Claims 11-17, 19-20, 44-46, 54-68, 73-77, 79-82, 113 and 135 are included in the rejection as they depend on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 14-15, 18-20, 43-46, 54-61, 66-69, 73-81, 105-106, 110-113, 132-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. (US PGPUB No. 2001/0012636) in view of Cherukuri et al. (US Patent No. 4971787) as evidenced by Gurol (US Patent No. 6669928).

Applicant Claims

Applicant claims a method of providing a supplement comprising the steps of : contain an amount of a separate calcium supplement in a distribution container; selecting a plurality of saliva pH test trips; establishing a separate saliva pH test strip procedures: compactly assembling said plurality of saliva pH test strips; attaching said compactly assembled plurality of saliva pH test strips to said distribution container; externally displaying the presence of said plurality of saliva pH test strips to potential purchasers of said calcium supplement; providing said amount of said calcium supplement to a purchaser; and providing said compactly assembled plurality of saliva pH test strips to said purchaser of said calcium supplement at about the time of accomplishing said step of providing said amount of said calcium supplement to a purchaser.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Azar et al. is directed to chewing gum with pH indicator. A kit is provided that contains a chewing gum and one or more pH sensitive members including at lease one pH sensitive substance (abstract). Figure 8 is directed to the container for the kit. It comprises one housing member for the pH sensitive members (i.e. pH test strips) and another housing member for the gum. It is taught that the pH sensitive members are for checking the pH level of oral fluids (paragraph 0071). It is taught that provided the pH does not drop below 5.3, the dental enamel remains intact but below this level crystals of apatite dissolve. If the pH returns fairly rapidly above 5.3, the ions will go back into the enamel and recrystallize. This recrystalliztion take longer in an acid environment (paragraph 0003). It is taught that the kit allows for checking the pH levels in one's saliva and oral fluids (paragraph 007). It is taught that the consumer chewing the gum would use the gum for raising the pH level in the mouth after a meal, a snack, sugar drink, or consuming food or drink leading to oral acidification. The indicator provides an estimation of the approximate time for which the chewing gum needs to be continued in order to reach the desired pH level (paragraph 0080). It is taught that the user may elect to perform the pH checks at any time before, during and after the chewing of the gum (paragraph 0171). Figure 5G is directed to diagram illustrating a reference color scale. This reference color scale provides a way for the user to compare the color of the scale to those on the indicator to determine the respective pH of the saliva (paragraph 0142). It is taught that the pH sensitive substrate undergoes a visibly detectable color change when exposed to saliva or oral fluids (paragraph 0118).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Azar et al. do not teach that the gum comprises calcium. However, this deficiency is cured by Cherukuri et al.

Cherukuri et al. is directed to an antacid chewing gum. The invention is directed to a chewing gum useful for delivery of measured doses of antacids (column 1, lines 16-18). Examples of antacids include calcium in the form of insoluble calcium salts which allows for a delivery system for supplemental calcium. It is taught that the need for supplemental calcium has recently been discovered in mature and older women particularly after they reach menopause. Additionally calcium used to treat osteoporosis (column 8, lines 4-12).

As evidenced by Gurol, alkaline substances afford both rapid and long-lasting antacid activity in the amount. Antacid activity refers to the ability of a substance to neutralize and/or buffer an acid (column 2, lines 61-66).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Azar et al. and Cherukuri et al. and incorporated calcium into the chewing gum of Azar et al. One of ordinary skill in the art would have been motivated to incorporate calcium for the added benefit of an antacid (which would be expected to increase oral pH as evidenced by Gurol) as well as a delivery system for supplemental calcium as taught by Cherukuri et al. Since the chewing gum of Azar et al. is designed to increase the pH of the mouth after a meal, a snack, sugar drink, or consuming food or drink that leads to oral acidification, one of ordinary skill in the art would expect that the addition of an antacid would have an

added benefit of aiding the increase of the pH which is what is desirable for the gum of Azar et al.

Regarding instant claims 14-15, Figure 8 of Azar et al. is more of a rectangular shaped container. The limitation of a bottle and cap is merely a design feature and imparts no critically to the actual composition. **Note MPEP 2144.04:** "if the feature is ornamentation only or does not have a mechanical function then it can not be patentably distinguished from the prior art.

Regarding the limitation that the test modality is compactly assembled to the distribution container, figure 8 clearly shows that the housing member for the test strips is attached directed to the housing member for the supplements.

Regarding the limitation of an information display, it would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al. and Cherukuri et al. and utilize a kit for the supplement and test strips. One of ordinary skill in the art would have been motivated to utilize a kit in order to package and ship the formulation as well as to provide instructions for a consumer/provider on how to utilize the product. "Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). **See MPEP 2112.01 [R-3].** The applicant has not indicated that the instructions indicate some unobvious functional relationship between the product and the instructions.

Regarding the no-cost increment limitation, since Azar et al. teach the strips and gum in the same container, there is a reasonable expectation that when sold the whole

device would be priced at one amount and the inclusion of the strips would not cost the consumer more.

Regarding the claimed time frame of test yields, Azar et al. teach the pH indicator changes color upon contact with the saliva or oral fluids. Azar et al. do not state how long it takes for this to occur. A reasonable interpretation would be that it happens rather quickly. Applicants have claimed that the test results can occur within 300 seconds, which is a time frame that can reasonably be interpreted from the teachings of Azar et al. Additionally, based on applicants description of the pH test strips as compared to those of Azar et al., it would appear that the test strips would yield results in similar if not the same time frame as instantly claimed.

Regarding claims 67-69, Azar et al. teaches that the test is performed after a meal, a snack, sugar drink, or consuming food or drink leading to oral acidification. Therefore, it would read on meal type test.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 11-12, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. in view of Cherukuri et al. as evidenced by Gurol

and in further view of Potter (US Patent No. 3217874) and Vette (US Patent No. 6302301).

Applicant Claims

Applicant claims that the container is sealed and utilized a tamper-proof seal.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Azar et al. and Cherukuri et al. are set forth above. Specifically, Azar et al. is directed to a kit comprising saliva pH test strips and chewing gum. Cherukuri et al. is directed to chewing gum comprising supplemental calcium.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Azar et al. and Cherukuri et al. do not claim that the container is sealed or contains a tamper-proof seal. However, these deficiencies are cured by Potter and Vette.

Potter is directed to packaging for a plurality of containers. It is taught that when packaging two or more containers utilizing a thermoplastic film and shrinking and closely fitting said film around the containers provides a stronger, more durable and attractive packages as compared to the prior art (column 1, lines 9-15 and 67-71, column 2, lines 1-2). The shrink wrapping allows for the contents of the containers to be visible through the package (column 1, lines, 58-59).

Vette is directed to dispensing container with a sliding vale and tamper-proof device. Figure 3 is directed to a device with a similar shape to that of Azar et al. It is taught that these devices prevent unwanted opening of a package container and in the

case of unauthorized opening allows the user to see that it has been opened (column 1, lines 7-10). The device comprises a sealing strip and a cover (column 8, lines 14-21).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al., Cherukuri et al., Potter and Vette and utilize shrink wrapping around the container. One of ordinary skill in the art would have been motivated to utilize shrink wrapping to provide a stronger, more durable and attractive package as taught by Potter.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al., Cherukuri et al., Potter and Vette and utilize a tamper-proof device. One of ordinary skill in the art would have been motivated to utilize the tamper proof device of Vette for the container of Azar et al. Both devices are directed to similar shaped devices and Vette teach that their device provides unwanted opening of a package container and allows for notification of unauthorized opening.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. in view of Cherukuri et al. as evidenced by Gurol and in further view of Assoumani (Agro Food Industry Hi-Tech, 1998).

Applicant Claims

Applicant claims a coral calcium supplement.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Azar et al. and Cherukuri et al. are set forth above. Specifically, Azar et al. is directed to a kit comprising saliva pH test strips and chewing gum. Cherukuri et al. is directed to chewing gum comprising supplemental calcium.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Azar et al. and Cherukuri et al. do not specify that the calcium is coral calcium. However, this deficiency is cured by Assoumani.

Assoumani is directed to the physical-chemical properties of calcium sources. It is taught that aquamin, which is a seaweed derived calcium, provides the best buffering capacity (figure 2) and is an excellent antacid product (page 34, third column, second paragraph).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al., Cherukuri et al., and Assoumani and utilize aquamin as the calcium source. One of ordinary skill in the art would have been motivated to utilize

aquamin as it is taught as providing the best buffering capacity out of other calcium sources tested and is an excellent antacid product as taught by Assoumani.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 62-65, 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. in view of Cherukuri et al. and in further view of Brown et al. (US Patent No. 5879163).

Applicant Claims

Applicant claims an internet-based recording system.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Azar et al. and Cherukuri et al. are set forth above. Specifically, Azar et al. is directed to a kit comprising saliva pH test strips and chewing gum. Cherukuri et al. is directed to chewing gum comprising supplemental calcium.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Azar et al. and Cherukuri et al. do not claim an internet-based recording system. However, this deficiency is cured by Brown et al.

Brown et al. is directed to an automated system which include a questionnaire generator for questioning the individual to determine their motivational drivers and

comprehension capacity, a profile generator, a translator which receives clinical data relating to a current health condition of the individual and translate that clinical data into a profile code. An evaluation program which evaluates education responses and provides profile updates for targeting subsequent educational material (abstract). The automated system is connected to the remote terminal via a communication network (column 4, lines 58-59). The communication network is a public network such as the internet (column 6, lines 49-51). The translator receives updated clinical data to determine if an individual has made an improvement and generates a new profile code for targeting education material to the individual (column 11, lines 49-44). The invention is to provide an automated system and method for customized health education (column 4, lines 36-39).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Azar et al. Cherukuri et al. and Brown et al. and utilize the automated system of Brown et al. for monitoring the progress of an individual. One of ordinary skill in the art would have been motivated to utilize the system of Brown et al. as it provides a means to evaluate and educate the consumer on heath related issues. It provides a way to track and monitor an individual's progress and provide updated profiles with new information so the individual can reach specific goals. It also provides motivational drivers for individuals to help them meet their heath related goals thereby allowing greater consumer compliance.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) the Azar reference involves on a pH test to encourage gum chewing and does not involve a separate supplement or any supplement. Applicants argue that (2) Azar provides no separate supplement is involved and no aspect of providing a user separate supplement-relevant information is indicated in any way. Applicants argue that (3) while Cherukuri teaches utilizing a gum delivery vehicle for an antacid, there is no connection between the pH testing to encourage gum chewing. It was he present invention that provides this significant link. Applicants argue that (4) claims 60 and 61 involve a recordation system and no comment as to these claims have been provided. Applicants argue that (5) instant claims 62-65 involve the benefit of having an internet based recording system to enhance the value to the purchaser and to encourage use. However Brown only involves a motivation driver and comprehension capability coding system. This ahs nothing to do with supplement sue. Applicants argue that (6) no rejections have been made of 67-68.

Applicants' arguments filed May 29 2009 have been fully considered but they are not persuasive.

Regarding applicants' first argument, the Azar references teaches separate pH test strips and a separate chewing gum. Therefore, the gum and test are taught as separate. The gum is designed to combat a drop in pH after eating or drinking. Therefore, it supplements the deficiency of a low pH. Therefore, it would read on a supplement. It does not teach the incorporation of calcium. For that reason Cherukuri et al. is relied upon.

Regarding applicants' second argument, the gum is specifically designed to supplement the drop in pH associated with eating/drinking. Therefore, it is treating that deficiency. Azar et al. teach that the pH test strips are designed to inform the user of the approximate remaining chewing time. Therefore, it clearly teaches providing to the user separate supplement-relevant information.

Regarding applicants' third argument, Cherukuri et al. is directed to an antacid chewing gum. An antacid by design is utilized to neutralize or buffer the pH. Since Azar et al. teach that this is the design of the chewing gum (i.e. increase pH); this provides the link between the teachings of Cherukuri et al. and the pH test strips. One of ordinary skill in the art would have been motivated to add an antacid in order to aid the gum of Azar et al. in increasing the pH following drinking/eating.

Regarding applicants' fourth argument, the pH test strips would indicate the pH of the oral cavity. Therefore, it would really record what the pH of the mouth is, meeting the limitations of claims 60 and 61.

Regarding applicants' fifth argument, Azar et al. is directed to oral hygiene in the sense that the invention is utilized to help reduce plaque acidification and aid in

remineralization. The invention of Brown provides a means to evaluate and educate the consumer on heath related issues. It provides a way to track and monitor an individual's progress and provide updated profiles with new information so the individual can reach specific goals. It also provides motivational drivers for individuals to help them meet their heath related goals thereby allowing greater consumer compliance. Sine oral hygiene is a health related issue, the combination of Brown and Azar et al. would provide the motivation for a user to increase their knowledge and meet their health related goals as they pertain to oral hygiene.

Regarding applicants' sixth argument, the examiner has corrected this inadvertent typo. The claims are clearly rejected as claim 69 depends form 67 and 68 and the teachings of Azar et al. clearly teach that the test meal time test.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 18-20, 43, 45-46, 54-69, 73-82, 105-106, 110-113, 132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckers (US Patent No. 5019974).

Applicant Claims

The instant application claims a method of making a supplement available comprising the steps of: containing a separate amount of said supplement by a distribution container; selecting a separate test modality relevant to some aspect in conjunction with use of said supplement; establishing a procedure for use of said

separate test modality; compactly assembling said separate test modality; and providing said compactly assembled separate test modality for distribution in association with said distribution container.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Beckers is directed to diabetes management system and apparatus. The system and apparatus are for efficient medical control of a medical condition such as diabetes. The system and apparatus comprise a recorder, an interface and a master computer. The master computer develops a program of therapy which is downloaded into the recorder which then remind the patient of any therapy due and records that the therapy has been effected. The recorder is subsequently fed back to the master computer to improve or alert the therapy programme (abstract). The patient enters into the memory of the recorder information relating to insulin types and doses, diet, exercise, urine test results, hypoglycemic reactions and special events. The recorder also incorporates a blood glucose test strip reader and stores the measured value in the memory (column 2, lines 27-37). For insulin therapy there is an alarm that goes off and lets the patient know it is time to take his/her insulin. After the patient has taken the correct dose of insulin, the press the correct key to confirm (column 4, lines 1-29). Other tests include urine test strip for determine urine glucose (column 5, lines 55-64). A blood glucose test strip reader is utilized for determining blood glucose (column 6, lines 63-68). The recorder is used with an interface unit to enable data to be transferred between the recorder and the master computer (i.e. the data is sent in) (column 9, lines 24-32). A procedure for using the test is taught (columns 5-6, lines 67-68 and 1-11). Print-outs of

the blood-glucose values, insulin values, etc. can be generated via the interface with either phone-modem communication or direct communication (column 10). The recorder prompts the patient to perform the actions according to the program at the appropriate time (column 2, lines 27-35). For blood glucose reading a patient inserts a clean strip for a baseline then blood is introduced to the strip and recorded. Times for the test listed include up to 60 seconds and up to 120 seconds (column 6, lines 19-35).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Beckers does not specify making the diabetes management system and apparatus available in conjunction with the insulin. However, the management system and apparatus are designed to be utilized with insulin therapy.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to make the diabetes management system and apparatus available at the same time insulin is distributed. One of ordinary skill in the art would have been motivated to make the insulin available with the system as the system is designed to be utilized with insulin therapy to help the patient manage their diabetes. Furthermore, one of the steps of the procedure of the system is to alert the patient to take their insulin and then record the results. Therefore Beckers suggest utilizing the system in combination with insulin.

Regarding the no-cost increment, this is design choice. Whether or not the seller charges for the system when it is going to be utilized in combination with insulin does not result in a patentable distinguishing.

Regarding claims 57-58, since both urine and blood glucose are different test methods taught, a multiple test regimen is taught.

Regarding claims 60-64, the test strips provide a way to manual record the test. Then the information can be transmitted to a separate commuter (i.e. internet based system) where results can be tracked and printed out.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 18-20, 43, 45-46, 54-69, 73-82, 105-106, 110-113, 132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaish (US Patent No. 5501231).

Applicant Claims

The instant application claims a method of making a supplement available comprising the steps of: containing a separate amount of said supplement by a distribution container; selecting a separate test modality relevant to some aspect in conjunction with use of said supplement; establishing a procedure for use of said

separate test modality; compactly assembling said separate test modality; and providing said compactly assembled separate test modality for distribution in association with said distribution container.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kaish is directed to a patient operated instrument and method for testing and recording a biological condition of the patient. The system measure the forced peak expiratory flow of air expelled by the patient when blowing into a measuring tube (column 1, lines 8-14). The method of using the system is wherein the patient presses on button through and the system goes through a self test, if the test is unsuccessful the system will prompt the user to change the system batteries for powder supply or signal the operator that the device should be returned. After blowing into the tube the system will measure the signal to see if it is acceptable. After three good results are obtained the processor process the biological data stored in memory and indicates that the test has been completed (column 6, lines 1-30). The system lets the patient known that it is time for the test by the means of an alarm. Before shutting down the system can remind the patient to take the prescribed medication and displays the dosages thereof that have been preprogrammed by the doctor (column 7, lines 12-35). Figure 6 shows how the system is used in a physician's office to download the stored biological data and tie data into the physician's personal computer for subsequent analysis and printing (column 7, lines 63-65).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Kaish does not specify making the system available in conjunction with the prescribed medication. However, the system is designed to be utilized with medication.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to make the system available at the same time the medication is distributed. One of ordinary skill in the art would have been motivated to make the medication available with the system as the system is designed to be utilized with medication to help the patient manage their respiratory status. Furthermore, one of the steps of the procedure of the system is to alert the patient to take their medication. Therefore Kaish suggests utilizing the system in combination with the medication.

Regarding the no-cost increment, this is design choice. Whether or not the seller charges for the system when it is going to be utilized in combination with insulin does not result in a patentable distinguishing.

Regarding claims 57-58, since three tests are taken at a time, a multiple test regimen is taught.

Regarding claims 60-64, the device itself provides a way to manual record the test. Then the information can be transmitted to a separate commuter (i.e. internet based system) where results can be tracked and printed out.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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